



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/791,910	03/03/2004	Duane A. Burnett	CV06025US01	3844

24265 7590 10/24/2006

SCHERING-PLOUGH CORPORATION  
PATENT DEPARTMENT (K-6-1, 1990)  
2000 GALLOPING HILL ROAD  
KENILWORTH, NJ 07033-0530

EXAMINER

BERCH, MARK L

ART UNIT	PAPER NUMBER
----------	--------------

1624

DATE MAILED: 10/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Advisory Action</b> <b>Before the Filing of an Appeal Brief</b>	<b>Application No.</b> 10/791,910	<b>Applicant(s)</b> BURNETT ET AL.	
	<b>Examiner</b> Mark L. Berch	<b>Art Unit</b> 1624	

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 25 September 2006 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☐ The period for reply expires \_\_\_\_\_ months from the mailing date of the final rejection.  
 b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on \_\_\_\_\_. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

#### AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because  
 (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);  
 (b) ☒ They raise the issue of new matter (see NOTE below);  
 (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or  
 (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See memo. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).  
 5. ☒ Applicant's reply has overcome the following rejection(s): Dioxolanyl rejection see memo.  
 6. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).  
 7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.  
 The status of the claim(s) is (or will be) as follows:  
 Claim(s) allowed: \_\_\_\_\_  
 Claim(s) objected to: 19.  
 Claim(s) rejected: 1-5, 7-9, 12-18 and 20-23.  
 Claim(s) withdrawn from consideration: 10 and 11.

#### AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).  
 9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).  
 10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

#### REQUEST FOR RECONSIDERATION/OTHER

11. ☐ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: \_\_\_\_\_  
 12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). \_\_\_\_\_  
 13. ☐ Other: \_\_\_\_\_

Mark L. Berch  
 Primary Examiner  
 Art Unit: 1624

### DETAILED ACTION

The amendment filed 09/25/2006 under 37 CFR 1.116 in reply to the final rejection has been considered but is not deemed to place the application in condition for allowance and will not be entered because: the amendment to claim 22 for some reason removed the requirement that the host be a mammal. Thus, the claim now covers e.g. lowering cholesterol in a non-mammal, such as a bird or fish. However, the specification is limited to mammal as host; see e.g. page 8, lines 16 and 21.

The amendment, had it been entered, would have overcome the enablement rejection. The rejection on substituted dioxolanyl is dropped.

The traverse of the other rejection is unpersuasive. Applicants again point to page 27, lines 3-13. As was stated previously: Note that one prepares a salt of an acid (e.g. the COOH) or a salt of a base (such as an amino group), not a salt of a cation. That is, one forms a salt by reacting the parent acid with a base (so as to exchange the proton of the acid with the cation of the base), or the parent base with an acid, so as to protonate the amine and form the ammonium salt, as is set forth in the specification. Thus, converting a compound into a salt (e.g. RCOOH is converted to RCOOK) does not alter the electrical neutrality or lack thereof of the original compound. In such a process, if R had a charge on it, it will still have a charge on it after the salt thereof has been formed. In this case, it simply appears that the specification forgot to provide a generic description for the counterion.

The material to which applicants point begins "Compounds of the invention with an amino group can form pharmaceutically acceptable salts with organic and inorganic acids. Examples of suitable acids for salt formation are hydrochloric..." This is

Art Unit: 1624

unrelated to the issue at hand. It describes a process in which an amino group is converted to its salt form. Thus, if A is rest of molecule, all R = alkyl,  $A-NRR' + HX \rightarrow A-NRR'H^+ X^-$ .

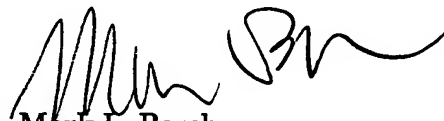
However, the moiety at hand does not have the form  $A-NRR'H^+$ . It has the form  $A-NRR'R''^+$ . That is, the process that page 27 refers to does not make, and cannot make, the trialkylammonium substituent. Indeed, the trialkylammonium substituent cannot be made at all by reacting an amine --- any amine --- with any acid such as those listed in the specification. The specification simply describes converting an amine into its corresponding salt. It is not a process which can fix a compound which lacks its counterion.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark L. Berch whose telephone number is 571-272-0663. The examiner can normally be reached on M-F 7:15 - 3:45.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on (571)272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1624

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Mark L. Berch  
Primary Examiner  
Art Unit 1624

10/19/2006